K070117

5. 510(k) Summary

AUG - 6 2007

Submitted on behalf of:

Dolomite Biotech Sdn. Bhd
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By official correspondent and contact:

Timothy Liew
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Date Prepared: 01/05/2007

Proprietary Name: Safe Plus Disposable Safety Syringe
Common Name: Piston Syringe
Classification Name: Piston Syringe
Class: II
Panel: 80
Product Code: MEG – Antistick Syringe

Predicate Device:
SEZ Safety Syringe by SEZ Corporation (K031163)

Device Description:
The Safe Plus Disposable Syringe is a single use hypodermic syringe similar to a traditional syringe in application and function except for its safety mechanism which when activated:

1. completely retracts and encloses the needle in the barrel thereby preventing finger access
2. renders the needle unusable again as it is crushed within the puncture resistant barrel.

No special techniques are required to use the safety mechanism and the user is clearly able to visualize the results when the sharps prevention feature has been activated.

Indications for Use:
The Safe Plus Disposable Safety Syringe is a sterile, non-toxic, non-pyrogenic, single-use, non-reusable, disposable manual retractable safety syringe in which medication can be injected into or fluid withdrawn from the human body. This device aids in prevention of needle stick injuries and reuse of the needle.

Safety and Effectiveness, comparison to predicate device

Device Name	**Predicate Device: SEZ Safety Syringe (K031163)**	**Safe Plus Disposable Safety Syringe**
Intended Use	This device is a safety hypodermic syringe for intramuscular and subcutaneous injection. This device aids in prevention of needle stick injuries.	Identical
Principal of Operation	Activation of safety feature consists of: 1. disassemble needle assembly from the plunger by turning the plunger 2. retract needle into the barrel and confine it by pushing plunger forward before disposal	Activation of safety feature consist of: 1. pushing the plunger forward until the gasket locks onto adaptor, hub and needle. 2. Identical
Volume	3 and 5 ml sizes	Identical
Nozzle Type	Female conical lock fitting with rotatable internally threaded neck	Identical
Barrel Marking	Scale: conforms to ISO 7886-1:1993(E).	Identical
Reuse	Non-reusable	Identical
Biocompatibility	Conforms to ISO 10993-1	Identical
Materials	1. Plastic parts: polypropylene (homo type) 2. Gasket: thermoplastic rubber 3. O-Ring: nitrile rubber 4. Packing film: Medipeel film	1. Identical 2. thermoplastic elastomer 3. thermoplastic elastomer 4. Polyester/polyethylene
Sterility	Sterilized by ethylene oxide gas SAL=10-6	Identical

Conclusion:

Based on tests performed in accordance with "Guidance for Industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features", "Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes" and internationally recognized standards for syringe performance, the Safe Plus Disposable Safety Syringe has been shown to be substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

Dolomite Biotech Sdn Bhd
C/O Mr. Timothy Liew
President
Epitome Enterprises
417 Whitney Street
San Leandro, California 94577

Re: K070117
Trade/Device Name: Safe Plus Disposable 2.5, 3cc syringes with needles 23 g x 1 inch, 25 g x 1 inch and 5 cc syringes with needles 21g x 1 ½ inches, 20g x 1 inch, 20g x 1 ½ inches and 21g x 1 inch
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: June 4, 2007
Received: June 11, 2007

Dear Mr. Liew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070117

4. Indications for Use

510(k) Number (if known): K070117

Device Name: Safe Plus Disposable Safety Syringe

Indications for Use:

The Safe Plus Disposable Safety Syringe is an ETO sterile, non-toxic, non-pyrogenic, latex free, single-use, non-reusable, disposable manual retractable safety syringe in which medication can be injected into or fluid withdrawn from the human body. This device aids in prevention of needle stick injuries and reuse of the needle.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K070117